

## CLAIMS

What is claimed is:

1. A lateral flow assay device for quantitative detection of target analytes in a sample,

said device comprising:

an assay support member having a first end and a second end;

a sample receiving element at one end of said support member for introduction of the sample to be analyzed to said device; and

an immunoassay test strip comprising:

a porous analytical membrane removably mounted adjacent to and generally parallel

with said support member, said analytical membrane having a first end and a second end;

at least one capture region in said analytical membrane intermediate said first and second ends thereof, said at least one capture region being configured to capture labeled analytes moving from said first end of said analytical membrane toward said second end of said analytical membrane; and

a backing member between said analytical membrane and said support member to facilitate removal of said analytical membrane from said support member for reading the assay and for archiving said test strip.

2. The device recited in claim 1, and further comprising a protective membrane covering

said analytical membrane on the side opposite to said support member, said protective membrane being optically non-transparent.

3. The device recited in claim 2, wherein said protective membrane is formed integrally  
with said porous membrane.

4. The device recited in claim 2, wherein said protective membrane is formed pursuant  
to a surface treatment of said porous membrane.

5. The device recited in claim 1, and further comprising a control region in said porous  
membrane for collection of magnetic conjugates that have passed the capture region to show that  
said test strip has been used.

6. The device recited in claim 2, and further comprising at least one magnetic  
calibration line printed on said protective membrane.

7. The device recited in claim 2, wherein said protective membrane is formed of  
material selected from the group consisting of plastic, glass and paper.

8. The device recited in claim 1, and further comprising superparamagnetic conjugate  
particles in said sample receiving element, said particles being configured to bind with target  
analytes in the sample.

9. A lateral flow assay device for quantitative detection of target analytes in a sample,  
said device comprising:

an assay support member having a first end and a second end;

4 a sample receiving element near one end of said support member for introduction of the  
sample to be analyzed to said device; and

6 an immunoassay test strip comprising:

a porous analytical membrane removably mounted adjacent to and generally parallel  
8 with said support member, said analytical membrane having a first end and a second end;

superparamagnetic conjugate particles in said sample receiving element configured  
10 to bind with the target analytes in the sample;

a capture region in said analytical membrane intermediate to said first and second  
12 ends thereof, said capture region being configured to capture labeled analytes moving from  
said first end of said analytical membrane toward said second end of said analytical  
14 membrane; and

a backing member between said analytical membrane and said support member to  
16 facilitate removal of said analytical membrane from said support member for reading the  
assay and for archiving said test strip.

10. The device recited in claim 9, and further comprising a protective membrane covering  
2 said analytical membrane on the side opposite to said support member, said protective membrane  
being optically non-transparent.

4  
11. The device recited in claim 10, wherein said protective membrane is formed  
6 integrally with said porous membrane.

8 12. An analytical immunoassay apparatus for quantitative detection of target analytes

in a sample, said apparatus comprising:

- 10                    an assay support member having a first end and a second end;  
                      a sample receiving element near one end of said support member for introduction of  
12                    the sample to be analyzed to said apparatus;  
                      an immunoassay test strip comprising:  
14                    a porous analytical membrane removably mounted adjacent to and generally parallel  
                      with said support member, said analytical membrane having a first end and a second end;  
16                    superparamagnetic conjugate particles in said sample receiving element configured  
                      to bind with the target analytes in the sample;  
18                    a capture region in said analytical membrane intermediate to said first and second  
                      ends of said analytical membrane, said capture region being configured to capture labeled  
20                    analytes moving from said first end of said analytical membrane toward said second end of  
                      said analytical membrane; and  
22                    a backing member between said analytical membrane and said support member to  
                      facilitate removal of said analytical membrane from said support member for selectively  
24                    reading the assay and archiving said test strip; and  
                      a magnetic reader device for determining the presence and quantity of magnetic conjugate  
26                    particle labeled target analytes in said capture region, said reader device being shaped and configured  
                      to receive said test strip after the lateral flow process has been completed.

13. The apparatus recited in claim 12, and further comprising a protective membrane  
2                    covering said analytical membrane on the side opposite to said support member, said protective  
                      membrane being optically non-transparent.

14. The apparatus recited in claim 13, wherein said protective membrane is formed

integrally with said porous membrane.

15. A method for conducting a lateral flow immunoassay quantitative detection of target

analytes in a sample, a method comprising:

applying the sample to one end of the porous membrane of a lateral flow test strip;

coupling superparamagnetic conjugate particles residing in the test strip at said one end, the superparamagnetic particles being treated to bind with any target analyte in the sample;

capturing the bound complexes of analyte and superparamagnetic particles in the capture region of the porous membrane as the sample and bound complexes move through the porous membrane by capillary action;

reading the quantity of labeled analytes in the capture region; and

providing an output representative of the quantity of labeled analytes in the capture region.

16. The method recited in claim 15, and further comprising removing the test strip from the

lateral flow assay device with the bound complexes remaining available to be selectively stored and sensed as to the quantity of the bound complexes in the capture region.